## SECTION 1: PRODUCT IDENTIFICATION

<table>
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<tr>
<th>PRODUCT NAME</th>
<th>GABAPENTIN, USP</th>
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<tr>
<td>PRODUCT CODE</td>
<td>2461</td>
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**SUPPLIER**

- **MEDISCA Inc.**
  Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855
  661 Route 3, Unit C, Plattsburgh, NY, 12901
  3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
  6641 N. Belt Line Road, Suite 130, Irving, TX, 75063

- **MEDISCA Pharmaceutique Inc.**
  Tel.: 1.800.665.6334 | Fax.: 514.338.1693
  4509 Rue Dobrin, St. Laurent, QC, H4R 2L8
  21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2

- **MEDISCA Australia PTY LTD**
  Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047
  Unit 7, Heritage Business Park
  5-9 Ricketty Street, Mascot, NSW 2020

**EMERGENCY PHONE**

- CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
- NSW Poisons Information Centre: 131 126

**USES**

- Anticonvulsant; analgesic.

## SECTION 2: HAZARDS IDENTIFICATION

<table>
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<tr>
<th>GHS CLASSIFICATION</th>
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<tr>
<td>SIGNAL WORD</td>
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<tr>
<td>HAZARD STATEMENT(S)</td>
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<tr>
<td>AUSTRALIA-ONLY HAZARDS</td>
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</table>

**PRECAUTIONARY STATEMENT(S)**

- **Prevention** Not applicable
- **Response** Not applicable
- **Storage** Not applicable
- **Disposal** Not applicable

<table>
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<tr>
<th>HMIS CLASSIFICATION</th>
<th>Health Hazard</th>
<th>Flammability</th>
<th>Reactivity</th>
<th>Personal Protection</th>
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## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<table>
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<tr>
<th>CHEMICAL NAME</th>
<th>1-(Aminomethyl)-cyclohexaneacetic acid</th>
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<td>CAS NUMBER</td>
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<tr>
<td>ALTERNATE CAS NUMBER</td>
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MOLECULAR WEIGHT

171.2383

COMPOSITION

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<td>GABAPENTIN</td>
<td>60142-96-3</td>
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There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

Gabapentin is an analogue of gamma-aminobutyric acid (GABA), but it is neither a GABA agonist nor antagonist and its mechanism of action is unknown.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT
Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT
Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED
Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED
Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL
Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
Dust explosion properties:
Kst: 270 bar.m/s
Minimum ignition energy (MIE) - dust cloud: < 3 mJ

FLAMMABLE PROPERTIES
May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS
Under fire conditions, hazardous fumes will be present.

EXTINGUISHING MEDIA
Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS
Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT
On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE
Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.
SECTION 7: HANDLING AND STORAGE

**PRECAUTIONS FOR SAFE HANDLING**
Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

**STORAGE CONDITIONS**
Store in original container, tightly sealed container, protected from direct sunlight, in a dry, cool and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Preserve in well-closed containers. Store at room temperature.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

**Chemical Name:** GABAPENTIN  **CAS #: 60142-96-3**

<table>
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<tr>
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<th>TWA</th>
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N/L = Not Listed

**EXPOSURE GUIDELINES**
Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m3.

**PERSONAL PROTECTIVE EQUIPMENT**
Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA’s eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

**SPECIFIC ENGINEERING CONTROLS**
Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

**NOTES**
USP Industrial Use TWA: 1200 µg/m^3

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

**PHYSICAL STATE**
Solid

**DESCRIPTION**
White to off-white, crystalline solid.

**SOLUBILITY**
Freely soluble in water and in alkaline and acidic solutions.

**ODOR**
Not available

**FLAMMABILITY**
May be combustible at high temperature

**ODOR THRESHOLD**
Not available

**PH**
6.5 - 8 (2%)

**MELTING POINT**
(162 - 167)°C, (323.6 - 332.6)°F

**BOILING POINT**
Not available

**FREEZING POINT**
Not available

**FLASH POINT**
Not available
SAFETY DATA SHEET

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY
Not established

STABILITY
Stable under recommended storage conditions

MATERIALS TO AVOID
Strong oxidants

HAZARDOUS DECOMPOSITION PRODUCTS
Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur

HAZARDOUS POLYMERIZATION
Will not occur

POSSIBILITY OF HAZARDOUS REACTION
Not established

CONDITIONS TO AVOID
Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY
Oral: Rat: LD50: (mg/kg): > 5000
Dermal: Rabbit: LD50: (mg/kg): Not available
Inhalation: Rat: LD50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION
Due to lack of data the classification is not possible.

SERIOUS EYE DAMAGE/EYE IRRITATION
Irritancy test: Rabbit: Eye: Non-irritating
Based on available data, the classification criteria are not met.

RESPIRATORY OR SKIN SENSITIZATION
Due to lack of data the classification is not possible.

GERM CELL MUTAGENICITY
Due to lack of data the classification is not possible.
Data from germ cell mutagenicity tests were not found.
Ames assay: Negative
Chromosomal aberrations in Chinese hamster bone marrow: Negative
HGPRT forward mutation assay in Chinese hamster lung cells: Negative
Unscheduled DNA synthesis in rat hepatocytes: Negative

CARCINOGENICITY
OSHA
GABAPENTIN is not listed.

NTP
GABAPENTIN is not listed.

IARC
GABAPENTIN is not evaluated.

California Proposition 65
This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

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ADDITIONAL CARCINOGENICITY INFORMATION
Carcinogenicity study: Mouse: 2000 mg/kg/day for 2 years: Malignant pancreatic tumors in male rats but not female rats.
Carcinogenicity study: Mouse: < 2000 mg/kg/day for 2 years: Not carcinogenic.
Based on available data, the classification criteria are not met.

REPRODUCTIVE TOXICITY
Reproductivity study: Mouse: 1000 - 3000 mg/kg/day: Delayed bone ossification but no malformations.
Reproductivity study: Rat: 500 - 2000 mg/kg/day: At 500 mg/kg/day, increased the incidence of hydronephrosis in the offspring. At 2000 mg/kg/day no increase in other malformations of offspring.
Reproductivity study: Rabbit: 60 - 1500 mg/kg/day: Increased incidence of postimplantation loss but no increase in malformations of offspring.
Reproductivity study: Rat: < 2000 mg/kg/day: No adverse effects on fertility.
No adverse effects were reported in the infants from mothers taking gabapentin during pregnancy and while breast feeding, and the authors considered that gabapentin was generally safe during breast feeding.
Based on available data, the classification criteria are not met.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE
Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE
Due to lack of data the classification is not possible.

ASPIRATION HAZARDS
Not expected to present a significant hazard under anticipated conditions of normal use.

SIGNS AND SYMPTOMS OF EXPOSURE
May be harmful if inhaled. May cause respiratory tract irritation.
POTENTIAL HEALTH EFFECTS
Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion: May be harmful if swallowed.
Skin: May be harmful if absorbed through skin. May cause skin irritation.
Eyes: May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION
TOXICITY
EC50: 48 Hr: Daphnia magna: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): Not available
IC50: 72 Hr: Algae: (mg/L): Not available

PERSISTENCE AND DEGRADABILITY
Not available

BIOACCUMULATIVE POTENTIAL
Log Pow: -1.31 (20°C).

MOBILITY IN SOIL
Water Solubility: 4490 mg/L (25°C)
Henry’s Law Constant: 1.81E-10 atm-m3/mole (25°C)

OTHER ADVERSE EFFECTS
This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS
WASTE DISPOSAL
Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

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SECTION 15: REGULATORY INFORMATION

<table>
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<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4 N/L</th>
<th>SAR A (Title III) 40 CFR Part 372.65 N/L</th>
<th>EPA 40 CFR Part 355 Appendix A N/L</th>
<th>Appendix B N/L</th>
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<th>Right-to-know New Jersey N/L</th>
<th>Massachusetts N/L</th>
<th>California Prop 65 N/L</th>
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N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

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<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation Not Listed</th>
<th>Therapeutic Goods Act Not Listed</th>
<th>Code of Practices - Illicit Drug Precursors Not Listed</th>
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SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; GHS – Global Harmonized System; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; TWA – Time Weighted Average; HSIS – Hazardous Substances Information System; STEL – Short Term Exposure Limit; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 – Lethal Dose, 50%; IARC – International Agency for Research on Cancer; NTP – National Toxicology Program; WHMIS – Workplace Hazardous Materials Information System; SARA – Superfund Amendments and Reauthorization Act; EPA – Environmental Protection Agency; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; HMIS – Hazardous Materials Information System; NIOSH – National Institute for Occupational Safety and Health; MSHA – Mine Safety and Health Administration; ACGIH – American Conference of Governmental Industrial Hygienists; IDHL – Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL – Recommended Exposure Limit

LAST REVISION

11/2015
This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.